§ 493.61 Requirements for a certificate of accreditation.

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

(1) Meets the requirements of § 493.57 or, if applicable, § 493.49 of subpart C of this part; and

(2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must—

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of § 493.63;

(3) Comply with the requirements of the approved accreditation program;

(4) Permit random sample validation and complaint inspections as required in subpart Q of this part;

(5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;

(6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and

(7) Authorize its accreditation program to submit to HHS the results of the laboratory's proficiency testing.

(c) A laboratory failing to meet the requirements of this section—

(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program;

(2) Will be subject to full determination of compliance by HHS;

(3) May be subject to suspension, revocation or limitation of the laboratory's certificate of accreditation or certain alternative sanctions; and

(4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.

(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with § 488.11 of this chapter.

(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and

(3) Offer an opportunity for appeal as provided in subpart R of this part.

(f) If the laboratory requests a hearing within the time frame specified by HHS—

(1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.

(g) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or § 493.57.

(h) A laboratory seeking to renew its certificate of accreditation must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of accreditation;

(2) Meet the requirements of this subpart; and

(3) Submit the certificate of accreditation fee specified in subpart F of this part.

(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;

(3) The opportunity for appeal on HHS's action to deny the renewal application for certificate of accreditation as provided in subpart R of this

part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.

Laboratories issued a certificate of accreditation must:

(a) Notify HHS and the approved accreditation program within 30 days of any changes in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.

(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

SOURCE: 57 FR 34014, July 31, 1992, unless otherwise noted.

§ 493.501 General requirements for accredited laboratories.

(a) *Deemed status.* HCFA may deem a laboratory to meet all the applicable CLIA program requirements of this Part if the laboratory is accredited by a private, nonprofit accreditation organization for laboratories that—

(1) Provides reasonable assurance to HCFA that it requires the laboratories it accredits to meet all of the requirements equivalent to the CLIA condition level requirements specified in this part and would, therefore, meet condition level requirements if those laboratories had not been granted deemed status and had been inspected against condition level requirements; and

(2) Meets the requirements of § 493.506 of this subpart.

(b) *Laboratory requirements.* To be deemed to meet the applicable CLIA program requirements, a laboratory accredited by a private, nonprofit accreditation organization must—

(1) Authorize its accreditation organization to release to HCFA all records and information required by HCFA;

(2) Permit inspections as required by these regulations;

(3) Obtain a certificate of accreditation as required by § 493.632 of this part; and

(4) Pay the applicable fees as required by §§ 493.638 and 493.645 of this part.

(c) *Application and reapplication process for accreditation organizations.* In applying or reapplying to HCFA for deeming authority, a private nonprofit accreditation organization must provide the following information to the Administrator of HCFA—

(1) The specialty(ies) or subspecialty(ies) for which the organization is requesting ''deeming authority'';

(2) A detailed comparison of individual accreditation requirements with the comparable condition level requirements; i.e., a crosswalk;

(3) A detailed description of the inspection process, including the frequency of inspections, copies of inspection forms, instructions, and guidelines, a description of the review and decision-making process of accreditation inspections and a description of